

MSOP-038
PATENT APPLICATION

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Applicants: Rosen et al.
Serial No.: 09/937,192
Filing Date: 9/21/01
For : Methods and Compositions for Degradation and/or Inhibition of HER-
Family Tyrosine Kinases

Examiner: B. Kifle
Group Art Unit: 1624

RESPONSE TO OFFICIAL ACTION

This is in response to the Official Action mailed September 12, 2002 for the above-captioned application. Applicants request an extension of time and enclose the appropriate fee. The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 15-0610.

Reconsideration of the application in view of the remarks herein is respectfully requested.

The Examiner rejected claims 3, 4, 6 and 9-34 under 35 USC § 112, second paragraph. The Examiner asserts that the claims are indefinite because "the scope of the ansamycin antibiotic is unclear." Applicants point out that this rejection is not properly applied to claims 9, 18 and 24, in which both ansamycin antibiotics are identified as being geldanamycin. Moreover, Applicants respectfully submit that the term "ansamycin antibiotic" is a recognized term of art, as is apparent from searches on the internet or in the USPTO full text search engine.

For example, US Patent No. 4,247,462, entitled "Ansamycin Antibiotic" states that:

The ansamycins constitute a class of antibiotics characterized by an aliphatic bridge linking two nonadjacent positions of an aromatic nucleus. The rifamycins and

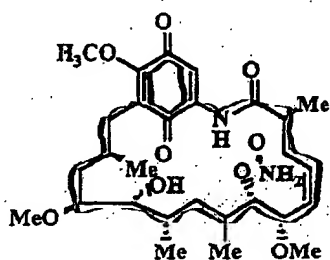
I hereby certify that this paper and any attachments named herein are being deposited with the US Postal Service as first-class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on 12 March 03.

Marina T. Larson
Marina T. Larson, PTO Reg. No. 32,038

12 March 03
Date of Signature

streptovaricins are well known members of this class of antibiotics. The chemistry of the ansamycin antibiotics is reviewed by K. L. Rinehart, Jr. and L. S. Shield in Progress in the Chemistry of Organic Natural Products, published by Springer-Verlag, Vienna-New York (1976).

See also, US Patent No. 4,738,958 entitled "Ansamycin antibiotic and its use as a medicament." When one takes the structure of geldanamycin for example, these definitions are applied as follows:



Geldanamycin (GM)

where the organic nucleus is indicated in red and the ansa ring is indicated in green
Applicants are not obligated to define terms used in accordance with their art recognized meaning. Thus, the person skilled in the art would fully recognize the scope of the claims.

The Examiner has also rejected claims 3, 4, 6 and 9-30 as lacking enablement. The Examiner states that "undue experimentation is required to use compounds of the instant claims to treat cancers generally or those which over-express a HER-family kinase." The basis for this argument is largely that the Examiner is classing cancer therapy with perpetual motion machines and assumes in assessing enablement that it is inherently unbelievable that a cancer therapy could work generally. Such may have been the case when *In re Buting* was decided in 1969, but the art and the law have progressed since then. The notion of automatic unbelievability is no longer

credited. Indeed, as the Board of Appeal noted in 1987 in *Ex parte Rubin*, 5 USPQ2d 1461, 1462 (POBAI 1987), "'contemporary knowledge in the art' has far advanced since the days when the any statement of utility in treating cancer was per se 'incredible.'" Here, the Examiner has not offered any reasoning as to why the assertions of general utility in this application, given the suggested mechanism of action, and the evidence of involvement of the targeted species in numerous different cancer types. As such, the Examiner has failed to meet the burden discussed in *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971), where it is noted that:

a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112, *unless* there is a reason to doubt the objective truth of the statements contained therein, which must be relied upon for an enabling disclosure.

A thirty-year-old case discussing the state of the art at that time, is not a reason to doubt the truth of the asserted utility here. The Examiner should either withdraw the rejection or address the merits of Applicants' previously submitted arguments and evidence (Amendment filed 7/22/02, Exhibits A-H).

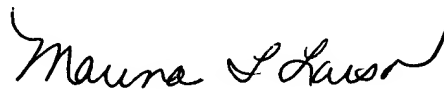
Applicants further point out that claims 3, 4, 6 and 9-11 are composition claims. Since the rejection under 35 USC § 112, first paragraph is not applied to all of the method claims (claims 31-34 are not rejected), it follows that the Examiner acknowledges that there is a disclosed believable utility for the compositions. An applicant is not required to disclose or enable every conceivable utility for a claimed composition, only some utility. In this regard, Applicants direct the Examiner to the decision in *In re Brana*, 34 USPQ2d 1436 (Fed. Cir. 1995) in which compositions which were said to have "anti-tumor activity" were found to meet the enablement/utility requirement because there were examples in specific tumor models which corresponded to specific diseases. Here, specific cancer types are named (and claimed in method claims 31-34). Thus, the facts of this case are even more clear cut than those in *Brana* because

MSK.P-038
PATENT APPLICATION

the specification directly names specific diseases for which the compositions can be used. Thus, the application of the rejection to the composition claims is in error and should be withdrawn for this additional reason.

In view of the foregoing amendments and arguments, Applicants submit that all claims are in form for allowance. Favorable reconsideration and allowance of all claims are respectfully urged.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Marina T. Larson".

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